DEC 2 4 2013

Section 5: 510(k) Summary

Venue 50

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 7, 2013
Submitter:	GE Healthcare 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Pernell Abrantes Regulatory Affairs Leader GE Healthcare T:(414) 647- 4422
Device: Trade Name:	Venue 50 Diagnostic Ultrasound System
Common/Usual Name:	Diagnostic Ultrasound System
Classification Names: Product Code:	Class II Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	Venue 40 - K112122 SonoSite Edge - K113156 LOGIQ e – K113690 LOGIQ S8 - K131527
Device Description:	The Venue 50 device is a compact and portable ultrasound system consisting of a hand-carried console approximately 282mm in height, 274mm in width and 56mm in depth. The console can be docked with a Docking station or mobile Docking cart. It has a 12.1" LCD display with finger-touch user interface. The single-surface screen can be sanitized and cleaned with medical grade disinfectants. Several connectivity options are available including DICOM.
Intended Use:	The Venue 50 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Ophthalmic; Fetal/OB; Abdominal (GYN & Urology);

Pediatric: Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Transvaginal; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures.

Technology: The Venue 50 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The Venue 50 system is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The Venue 50 and predicate Venue 40 systems have the same clinical intended use with the exception of Ophthalmic which is substantially equivalent to Ophthalmic on the SonoSite Edge (K113156).
- The Venue 50 and predicate Venue 40 systems have the same imaging modes.
- The Venue 50 and predicate Venue 40 systems transducers are identical accept for the 10C-SC which is similar in materials, manufacture and clinical capability to the 10C-D on the predicate LOGIQ S8 (K131527). The only difference is the connector.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The Venue 50 and predicate Venue 40 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The Venue 50 and predicate Venue 40 systems have been designed in compliance with approved electrical and physical safety standards.

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The Venue 50 and its applications comply with voluntary standards:

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices
8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Transducer material and other patient contact materials such as needle guidance kits are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Venue 50, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Venue 50 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

GE HEALTHCARE
BRYAN BEHN
REGULATORY AFFAIRS MANAGER
9900 INNOVATION DR. RP-2138
WAUWATOSA WI 53226

Re: K133431
Trade/Device Name: Venue 50 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: November 7, 2013
Received: November 8, 2013

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Venue 50 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

12L-SC	3S-SC
4C-SC	L8-18i-SC
E8CS-SC	10C-SC

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours.

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K133431

Device Name: Venue 50

Indications for Use:

The Venue 50 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Ophthalmic; Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Transvaginal; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures.

Prescription Use_X___ AND/OR Over-The-Counter Use_N/A_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use Form

GE Venue 50 Ultrasound

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation											
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse[b]	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic	N	N			N		N	N	N		
Fetal/OB	N	N			N		N	N	N		
Abdominal[1]	N	N			N		N	N	N		
Pediatric	N	N			N		N	N	N		
Small Organ (specify)[2]	N	N			N		N	N	N		
Neonatal Cephalic	N	N			N		N	N	N		
Adult Cephalic	N	N			N		N	N	N		
Cardiac[3]	N	N			N		N	N	N		
Peripheral Vascular	N	N			N		N	N	N		
Musculo-skeletal Conventional	N	N			N		N	N	N		
Musculo-skeletal Superficial	N	N			N		N	N	N		
Thoracic/Pleural (specify)[4]	N	N			N		N	N	N		
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal	N	N			N		N	N	N		
Intraoperative (specify)[5]	N	N			N		N	N	N		
Intraoperative Neurological											
Intravascular/Intraluminal											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage	N	N			N		N	N	N		
Vascular Access (IV, PICC)	N	N			N		N	N	N		
Nonvascular (specify)[6]	N	N			N		N	N	N		

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block;
[*] Combined modes are color/power Doppler with B-mode

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Venue 50 with 12L-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation											
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic	N	N			N		N	N	N		
Fetal/OB											
Abdominal[1]	P	P			P		P	P	P		
Pediatric	P	P			P		P	P	P		
Small Organ (specify)[2]	P	P			P		P	P	P		
Neonatal Cephalic	P	P			P		P	P	P		
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P			P		P	P	P		
Musculo-skeletal Conventional	P	P			P		P	P	P		
Musculo-skeletal Superficial	P	P			P		P	P	P		
Thoracic/Pleural (specify)[4]	P	P			P		P	P	P		
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)[5]	P	P			P		P	P	P		
Intraoperative Neurological											
Intravascular/Intraluminal											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P		
Vascular Access (IV, PICC)	P	P			P		P	P	P		
Nonvascular (specify)[6]	P	P			P		P	P	P		

N = new indication; P = previously cleared by FDA (K112122)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Venue 50 with 3S-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic	N	N			N		N	N	N		
Fetal/OB	P	P			P		P	P	P		
Abdominal[1]	P	P			P		P	P	P		
Pediatric	P	P			P		P	P	P		
Small Organ (specify)[2]											
Neonatal Cephalic	P	P			P		P	P	P		
Adult Cephalic	P	P			P		P	P	P		
Cardiac[3]	P	P			P		P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional	N	N			N		N	N	N		
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)[4]	P	P			P		P	P	P		
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)[5]	P	P			P		P	P	P		
Intraoperative Neurological											
Intravascular/Intraluminal											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P		
Vascular Access (IV, PICC)											
Nonvascular (specify)[6]											

N = new indication; P = previously cleared by FDA(K112122)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Venue 50 with 4C-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	P	P			P		P	P	P		
Abdominal[1]	P	P			P		P	P	P		
Pediatric	P	P			P		P	P	P		
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P			P		P	P	P		
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)[4]	P	P			P		P	P	P		
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)[5]	P	P			P		P	P	P		
Intraoperative Neurological											
Intravascular/Intraluminal											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P		
Vascular Access (IV, PICC)											
Nonvascular (specify)[6]	P	P			P		P	P	P		

N = new indication; P = previously cleared by FDA(K112122)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Venue 50 with L8-18i-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]	P	P			P		P	P	P		
Pediatric	P	P			P		P	P	P		
Small Organ (specify)[2]	P	P			P		P	P	P		
Neonatal Cephalic	P	P			P		P	P	P		
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P			P		P	P	P		
Musculo-skeletal Conventional	P	P			P		P	P	P		
Musculo-skeletal Superficial	P	P			P		P	P	P		
Thoracic/Pleural (specify)[4]	P	P			P		P	P	P		
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)[5]	P	P			P		P	P	P		
Intraoperative Neurological											
Intravascular/Intraluminal											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P		
Vascular Access (IV, PICC)	P	P			P		P	P	P		
Nonvascular (specify)[6]	P	P			P		P	P	P		

N = new indication; P = previously cleared by FDA(K112122)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Venue 50 with E8CS-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	P	P			P		P	P	P		
Abdominal[1]	P	P			P		P	P	P		
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)[4]											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal	P	P			P		P	P	P		
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular/Intraluminal											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage	N	N			N		N	N	N		
Vascular Access (IV, PICC)											
Nonvascular (specify)[6]											

N = new indication; P = previously cleared by FDA (K112122)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Venue 50 with 10C-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic	N	N			N		N	N	N		
Fetal/OB											
Abdominal[1]	N	N			N		N	N	N		
Pediatric	N	N			N		N	N	N		
Small Organ (specify)[2]	N	N			N		N	N	N		
Neonatal Cephalic	N	N			N		N	N	N		
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	N	N			N		N	N	N		
Thoracic/Pleural (specify)[4]	N	N			N		N	N	N		
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)[5]	N	N			N		N	N	N		
Intraoperative Neurological											
Intravascular/Intraluminal											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage											
Vascular Access (IV, PICC)											
Nonvascular (specify)[6]											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[*] Combined modes are color/power Doppler

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) Number_____